

Message Text

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ORIGIN HEW-06

INFO OCT-01 EUR-12 EA-12 ISO-00 OES-09 COME-00 EB-08
/048 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VO
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH:RFISCHER
EUR/CE:JHURLEY,JR(INFO)
EA/J:EFEATHESTONE(INFO)

-----092318 112102Z /70

P 111949Z JUL 78
FM SECSTATE WASHDC
TO AMEMBASSY BERN PRIORITY
AMEMBASSY TOKYO PRIORITY

UNCLAS STATE 174530

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, S,, JA

SUBJECT: FDA ADVISORY - LEAKING PULSATILE BYPASS PUMPS
(RECALL T-121-8)

1. FDA ADVISES OF THE FOLLOWING FIRM INITIATED RECALL:
PRODUCT INVOLVED - PULSATILE FLOW GENERATOR USED TO GIVE
PULSED QUALITY TO THE FLOW OF BLOOD FROM A HEART-LUNG
MACHINE DURING OPEN-HEART SURGERY. IT IS SOLD STERILE IN
A PLASTIC BLISTER PACK, IN CASES OF FIVE, IT IS AN
DISPOSABLE PRODUCT.

2. PRODUCT IDENTIFICATION - (A) PULSATILE BYPASS PUMP,
AVCO MEDICAL PRODUCTS, EVERETT, MASS. 01249. THERE ARE
NO PRIVATE LABELS. (B) S/N A7D...THRU M7D..., AND A8D...
THRU C8D.... AND LOT NOS. (STERILIZATION NO.) UP TO 31778
(MARCH 17, 1978) ARE UNDER RECALL. (A SIGNIFIES JANUARY
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B - FEBRUARY, ETC., 7-1977 ETC., D IS PRODUCT IDENT. AND
FOUR DIGIT UNIT NO.) S/N AND LOT NO. ARE ON THE UNIT
AND MASTER CTN. LABELS.

3. MANUFACTURER/RECALLING FIRM: AVCO MEDICAL PRODUCTS,
DIVISION OF AVCO CORP., 9 PLYMOUTH ST., EVERETT, MA 02149

4. REASON FOR RECALL - LEAKS IN THE NIPPLES CONNECTING THE BLOOD FLOW BALLONS TO THE BLOOD TUBING HAD BEEN REPORTED TO THE FIRM ORALLY BY TWO PHYSICIANS ON 5-10-78. FIRM INSPECTED THEIR STOCK AND FOUND EVIDENCE OF THE SAME PROBLEM. BOTH LEAKS HAVE BEEN FOUND DURING PRE-USE PURGING WITH SALINE SOLUTION. FIRM NOTICED FDA OF THE PROBLEM ON 5-11-78. AN EMPLOYEE OF AVCO'S SYSTEMS DIVN, AT THE FIRM TO TROUBLESHOOT FOR AVCO MEDICAL PRODUCTS DURING FDA'S INSPECTION, STATED THAT THE ULTRASONIC WELDING OF THE NIPPLES TO THE BODY OF THE GENERATOR WAS BEING DONE WITH A JIG WHICH GAVE LITTLE PROTECTION AGAINST BIASED WELDS, AND THAT A RESULT OF SUCH WELDS WOULD BE STRESS. HE FURTHER STATED THAT A CORNER OF THE NIPPLE WAS AT 90 DEGREES AT THE SITE WHERE THE CRACKS WERE APPEARING, AND THAT 90 DEGREE CORNERS ARE ANOTHER SOURCE OF STRESS IN THE MATERIAL OF WHICH THE BODY IS MADE. NO INJURIES OR DEATHS HAVE BEEN REPORTED.

5. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE BEEN ADVISED OF RECALL AND ACTION TO BE TAKEN - AVCO STATED THAT ALL PUMPS DESTRIIBUTED TO JAPAN AND EUROPE WERE USED ONLY FOR ANIMAL STUDIES. ANY QUESTIONS REGARDING RECALL SHOULD BE ADDRESSED TO FIRM.

6 FOREIGN CONSIGNEES AS PROVIDED BY FIRM TO FDA ARE:
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CARL RUDOW, KONTRON, ZURICH, SWITZERLAND

RONALD HAUSER, KONTRON, TOKYO, JAPAN CHRISTOPHER

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NNN

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TAGS: OGEN, ETRD, EIND, TBIO, US, JA
To: BERN TOKYO
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